4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1180]

Draft Guidance for Industry on Ensuring Safety of Animal Feed Maintained and Fed On-Farm;

Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry # 203 entitled "Ensuring Safety of Animal Feed Maintained and Fed On-Farm." This draft guidance is intended to help animal producers (persons who feed animals) develop and implement on-farm practices to ensure the safety of animal feed maintained and fed to animals on the farm.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Phares Okelo, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6862, email: phares.okelo@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry # 203 entitled "Ensuring Safety of Animal Feed Maintained and Fed On-Farm." This draft guidance is intended to help animal producers (persons who feed animals) develop and implement on-farm practices to ensure the safety of animal feed maintained and fed to animals on the farm. In this document, "farm" means animal production units such as integrated poultry grower operations, swine finishing units, and cattle feedlots. This document outlines basic measures that may be taken to maintain the safety of all types of feed held on the farm for use in animal production. This draft guidance recommends establishing measures to ensure the acquisition of safe feed and maintenance of its safety until the feed is offered to animals in the farm environment. This document does not address feed manufacture, which also may occur on farms.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the

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Agency's current thinking on this topic. It does not create or confer any rights for or on any

person and does not operate to bind FDA or the public. An alternative approach may be used if

such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

FDA concludes that there are no collections of information under the Paperwork

Reduction Act of 1995.

IV. Comments

Interested persons may submit either electronic comments regarding this document to

http://www.regulations.gov or written comments to the Division of Dockets Management (see

ADDRESSES). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be

seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday

and will be posted to the docket at http://www.regulations.gov.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either

http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/d

efault.htm or http://www.regulations.gov.

Dated: March 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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